DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

P980016

OCT - 9 1998

Ms. Jeanmarie Sales
Senior Product Regulation Manager
Tachyarrhythmia Management Business
Medtronic, Inc.
7000 Central Avenue, N.E.
Minneapolis, MN 55432-3576

Re: P980016
Medtronic® Model 7271 GEM™ DR Dual Chamber Implantable Cardioverter Defibrillator System with Model 9960 (GEM™ DR) Application Software, Medtronic® Model 6940 CapSureFix® Lead and Model 9466 Patient Magnet
Filed: May 11, 1998
Amended: June 9, July 17, August 7, September 14, 21, 22, and 25, and October 5, 1998

Dear Ms. Sales:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Medtronic® Model 7271 GEM™ DR Dual Chamber Implantable Cardioverter Defibrillator System with Model 9960 (GEM™ DR) Application Software, Medtronic® Model 6940 CapSureFix® Lead and Model 9466 Patient Magnet. This system is indicated for use in patients who are at risk of sudden death due to ventricular arrhythmias and have experienced one of the following situations: survival of at least one episode of cardiac arrest (manifested by loss of consciousness) due to a ventricular tachyarrhythmia or recurrent, poorly tolerated, sustained ventricular tachycardia. (Note: The clinical outcome for hemodynamically stable VT patients is not fully known. Safety and effectiveness studies have not been conducted.) We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval for Implantable Defibrillators and Programmers" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as

the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the postapproval requirements in the enclosure, the postapproval reports must include the following information: The same information as requested in items # 1-5, page 3 of the "Conditions of Approval for Implantable Defibrillators and Programmers" should be provided for the Medtronic® Model 6940 CapSureFix® Lead and subsequent leads approved under P980016.

Expiration dating for the Medtronic® Model 7271 GEM™ DR pulse generator has been established and approved at 18 months taking into account battery longevity. Expiration dating for the Medtronic® Model 6940 CapSureFix® Lead is 2 years post-sterilization.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Under section 519(e) of the act (as amended by the Safe Medical Devices Act in 1990), manufacturers of certain devices must track their products to the final user or patient so that devices can be located quickly if serious problems are occurring with the products. The tracking requirements apply to (1) permanent implants the failure of which would be reasonably likely to have serious adverse health consequences; (2) life sustaining or life supporting devices that are used outside of device user facilities the failure of which would be reasonably likely to have serious adverse health consequences; and (3) other devices that FDA has designated as requiring tracking. Under section 519(e), FDA believes that your device is a device that is subject to tracking because it is a permanent implant whose failure would be reasonably likely to have serious adverse consequences.

FDA's tracking regulations, published in the FEDERAL REGISTER on August 16, 1993, appear at 21 CFR Part 821. These regulations set out what you must do to track a device. In addition, the regulations list example permanent implant and life sustaining or life supporting devices that FDA believes must be tracked at 21 CFR 821.20(b) and the devices that FDA has designated for tracking at 21 CFR 821.20(c). FDA's rationale for identifying these devices is set out in the FEDERAL REGISTER (57 FR 10705-10709 (March 27, 1991), 57 FR 22973-22975 (May 29, 1992), and 58 FR 43451-43455 (August 16, 1993)).

If you have any questions concerning this approval order, please contact Doris Terry at (301) 443-8609 Ext-160.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Issued: 3-4-98

CONDITIONS OF APPROVAL
FOR IMPLANTABLE DEFIBRILLATORS AND PROGRAMMERS

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401) Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Boulevard, Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.
A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement by FDA Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1)Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2)Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:
(a)unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device. If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

In addition to the above and in order to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use, the annual postapproval reports shall include, separately for each model number (if applicable), the following information known by or reported to the applicant:

(1) The number of pulse generators domestically implanted and the number of reported explants and deaths.

(2) A breakdown of the reported deaths into pulse generator related and non-pulse generator related.

(3) A breakdown of the reported explants into the numbers reported at end of battery life, having complications unresolvable by programming and for other reasons with safety and effectiveness issues which can be derived from the reports stated.

(4) The number of pulse generators returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion and failed, with the failure mechanisms described.

(5) A cumulative survival table for the pulse generators.

(6) The number of programmers and modules shipped and the number of returns with a breakdown into the numbers currently in analysis, operating properly and failed, with the failure mechanisms described.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mix-up of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a)has not been addressed by the device's labeling or

(b)has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3)Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

(1)May have caused or contributed to a death or serious injury; or

(2)Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form

3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc. Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336) and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturer" (FOD # 987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers Assistance (DSMA) at 301-443-8818.

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. General Information

Device Generic Name:	Dual chamber implantable cardioverter defibrillator system and application software Steroid-eluting, bipolar, implantable, screw-in, atrial transvenous pace/sense lead Patient magnet
Device Trade Name:	Medtronic® Model 7271 GEM™ DR Dual Chamber Implantable Cardioverter Defibrillator System with Model 9960 (GEM™ DR) Application Software, Medtronic® Model 6940 CapSureFix® Lead and Model 9466 Patient Magnet
Sponsor Name and Address:	Medtronic, Inc. 7000 Central Avenue, N.E. Minneapolis, MN 55432
PMA Number:	P980016
Date of Panel Recommendation:	Not Applicable
Date of Notice of Approval to Applicant:	October 9, 1998

II. Indications and Usage

This device is indicated for use in patients who are at risk of sudden death due to ventricular arrhythmias and have experienced one of the following situations:

- survival of at least one episode of cardiac arrest (manifested by loss of consciousness) due to a ventricular tachyarrhythmia
- recurrent, poorly tolerated, sustained ventricular tachycardia (VT)

Note: The clinical outcome for hemodynamically stable VT patients is not fully known. Safety and effectiveness studies have not been conducted.

III. Device Description

The Model 7271 GEM™ DR Dual Chamber Implantable Cardioverter Defibrillator (ICD) System (the "GEM™ DR system") is a multiprogrammable, implantable cardioverter defibrillator that monitors and regulates a patient's heart rate by providing ventricular arrhythmia therapy and single or dual chamber bradycardia pacing.

The Model 7271 GEM™ DR ICD, along with the Model 6940 CapSureFix® or other compatible commercially available pace/ sense leads and cardioversion/ defibrillation leads, constitutes the implantable portion of the ICD system. The lead systems for the GEM™ DR system are implanted using either transvenous or transthoracic techniques.

The Model 9790C programmer, Model 9960E software, Model 9466 Patient Magnet, and a telemetry programming head constitute the external portion of the ICD system.

GEM™ DR ICD

The nomimal specifications of the GEM™ DR ICD are listed below:

Maximum Shock Energy	Defibrillation Lead[a,b,c,d] Connection	Pacing Lead[bd] Connection	Dimensions W x H x D	Volume	Mass
35 J	2 DF-1 (3.2 mm)	Two IS-1 Bipolar (3.2 mm)	57 x 82 x18 mm	62 cc	115 g
Case Material		Titanium			
Header Materials		Polyurethane, silicone rubber			
Power Supply		Lithium silver vanadium oxide (6.4 V nominal)			

[a]The ICD case serves as a defibrillation electrode.

[b]A list of compatible leads is provided in the labeling.

[c]The DF-1 ports will not accept a 3.2 mm in-line bipolar lead.

[d]DF-1 refers to the International Standard ISO 11318:1993. IS-1 refers to ISO 5841-3:1992(E).

Functionally, the GEM™ DR ICD is comparable to the commercially available Medtronic Jewel®/MicroJewel® family ICDs. The GEM™ DR system uses standard ICD therapies to treat ventricular tachycardia (VT), and ventricular fibrillation (VF): defibrillation, cardioversion, and antitachycardia pacing. Like the MicroJewel®, the GEM™ DR ICD case is an Active Can® that serves as one high-voltage electrode. The GEM™ DR uses the same core ventricular VT/VF detection criteria (intervals and number of intervals to detect) as the Jewel®/MicroJewel® ICDs.

The primary difference between the GEM™ DR and MicroJewel ICDs is the GEM™ DR uses a dual chamber PR Logic™ Pattern and Rate Analysis algorithm to discriminate between VT/VF and supraventricular tachyarrhythmias (SVT). The GEM™ DR uses the pattern and rate of sensed events in the atrium and ventricle to appropriately detect VT/VF and reject SVTs based upon programmed parameters. The GEM™ DR uses the same core VT/VF detection criteria as the MicroJewel® ICDs (intervals and number of intervals to detect), but builds on these criteria with three additional rejection rules for SVTs (atrial fibrillation/flutter, sinus tachycardia, other 1:1 SVT) which are programmable On/Off..

The GEM™ DR also provides dual chamber, rate responsive bradycardia pacing. The GEM™ DR rate responsive bradycardia pacing is similar to the commercially available Medtronic® Thera-i® family (approved 1/10/95) bradycardia pacemakers, with a maximum pacing rate of 120 bpm. The GEM™ DR uses a piezoelectric activity sensor to increase and decrease its pacing rate in response to the patient's detected activity level. The activity sensor is the same as that used in the Thera-i® pacemakers.

The GEM™ DR also has (1) ventricular rate stabilization, a rate-smoothing function;

(2) subthreshold lead impedance testing which allows lead impedance to be measured without administering a high voltage shock or pacing pulses that capture the heart; (3) a patient alert system which notifies the patient by audible tones if programmed conditions

occur (e.g., low battery voltage, out-of-range lead impedance); and (4) increased data storage and retrieval capabilities as compared to the MicroJewel® ICD.

MODEL 9960 (GEM™ DR) SOFTWARE

The Model 9960 (GEM™ DR) software contains the programmer application for the GEM™ DR system. It is used with the commercially available Model 9790C programmers to program the GEM™ DR ICD. The Model 9960 application software runs on the commercially available Model 9891 baseline software.

MODEL 9466 PATIENT MAGNET

The Model 9466 patient magnet is a blue-coated, ring-shaped magnet. It is identical to the commercially available Medtronic® Model 174105 Magnet, which has been marketed for use with pacemakers for over twenty years. Positioning a magnet over the ICD causes the Patient Alert™ status alarm to sound, if enabled. Automatic tachyarrhythmia detection is suspended while the magnet is positioned over the ICD, but bradycardia pacing is not affected.

MODEL 6940 CAPSUREFIX® LEAD

The Model 6940 CapSureFix® lead is a steroid-eluting, bipolar, implantable, screw-in, atrial transvenous pace/sense lead. It is identical to the commercially available Medtronic® Model 5068 CapSureFix® lead, except for the tip-to-ring spacing and the anchoring sleeve. The Model 6940 CapSureFix® or another compatible commercially available atrial pace/sense lead is used as part of the GEM™ DR system for pacing and sensing in the right atrium.

COMMERCIALLY AVAILABLE SYSTEM COMPONENTS

The commercially available components used as part of the GEM™ DR system include endocardial or epicardial pace/sense and cardioversion/defibrillation leads, the Model 9790C programmer, and the Model 9891 baseline software. The GEM™ DR system is compatible with commercially available implant support instruments and accessories used with the MicroJewel® ICD, including the Model 5358 defibrillation implant support device (DISD), Model 5705/5426 Active Can Emulator and Header (ACE) implant support device, Models 5420 and 5421 Patient Cables, Model 5429 Cable, and Model 5311 pacing system analyzer.

IV. Contraindications

Do not use the GEM™ DR system in:

- Patients whose ventricular tachyarrhythmias may have transient or reversible causes, such as:
  - acute myocardial infarction
  - digitalis intoxication
  - drowning
  - electrocution
  - electrolyte imbalance
  - hypoxia,
  - sepsis

- Patients with incessant VT or VF
- Patients who have a unipolar pacemaker
- Patients whose primary disorder is bradyarrhythmias or atrial arrhythmias

V. Warnings and Precautions

- **Resuscitation availability:** Do not perform ICD testing unless an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are readily available.
- **Lead system:** Do not use another manufacturer's lead system without demonstrated compatibility as undersensing of cardiac activity and failure to deliver necessary therapy could result.
- **Electrical isolation:** Do not permit the patient to contact grounded equipment which could produce hazardous leakage current. Resulting arrhythmia induction could result in the patient's death.
- **Avoiding shock during handling:** Program the ICD to OFF during surgical implant and explant, or post-mortem procedures, because the ICD can deliver a serious shock if you touch the defibrillation terminals while the ICD is charged.

STERILIZATION, STORAGE, AND HANDLING

- **Resterilization.** Do not resterilize and re-implant an explanted ICD.
- **"Use Before" Date.** Do not implant the ICD after the "Use Before" date, because the battery's longevity could be reduced.
- **If package is damaged.** Do not use the ICD or accessories if the packaging is wet; punctured, opened, or damaged, because the integrity of the sterile packaging might be compromised. Return the ICD to Medtronic.
- **ICD storage.** Store the ICD in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference to avoid ICD damage. Store and transport the ICD between -18 to 55 °C (0 to 131 °F), because temperatures outside this range could damage the ICD.
- **Equilibration.** Allow the ICD to reach room temperature before programming or implanting the ICD, because rapid temperature changes could affect initial ICD function.

IMPLANTATION AND ICD PROGRAMMING

- Infrequent charging of the high voltage capacitors could extend the ICD charge time. Program the ICD to condition the capacitors automatically, or perform a test charge to form the capacitors manually every six months (if the ICD has not charged to its maximum energy).
- Use only Medtronic programmers and application software to communicate with the ICD.
- Positioning a magnet or the programming head over the ICD suspends detection and treatment. The magnet does not alter bradycardia therapy.

- End of Life (EOL). Replace the ICD when the programmer displays an EOL message and a battery voltage of 4.57 volts or less. Immediate replacement is recommended if the programmer displays a Charge Circuit Timeout or Charge Circuit Inactive message.
- Program ICD parameters such as sensitivity thresholds and VT and VF detection intervals according to the recommendations in the technical manual.

LEAD EVALUATION AND LEAD CONNECTION

- For lead resterilization, use ethylene oxide only. Do not resterilize more than one time.
- Do not tie a ligature directly to the lead body, tie it too tightly, or otherwise create excessive strain at the insertion site as this can damage the lead.
- Do not immerse leads in mineral oil, silicone oil, or any other liquid.
- Do not grip the lead with surgical instruments.
- Do not use excessive force or surgical instruments to insert a stylet into a lead.
- Use the same polarity evaluated during testing when connecting the leads to the ICD to ensure defibrillation effectiveness.
- If a thoracotomy is required to place epicardial patches, it should be done during a separate procedure to reduce the risk of morbidity and mortality.
- Do not place the patch lead over nerve tissue as this can cause nerve damage.
- Place the patch lead with the conducting coil side facing the heart to ensure delivery of energy to the heart.
- Place the sutures well outside the coil of the patch lead or in the area between the coils to avoid possible coil fracture.
- If countershock is unsuccessful using external paddles, adjust the external paddle position (e.g., anterior-lateral to anterior- posterior) and be sure that the external paddle is not positioned over the patch.
- Do not fold, alter, or remove any portion of the patch, because it could compromise electrode function or longevity.
- Do not use ventricular transvenous leads in patients with tricuspid valve disease or a mechanical prosthetic tricuspid valve. Use with caution in patients with a bioprosthetic valve.
- Use the correct suture sleeve (when needed) for each lead to immobilize the lead and protect it against damage from ligatures.
- Ensure that the defibrillation lead impedance is greater than 10 ohms. An impedance below 10 ohms could damage the ICD.
- Do not kink the leads. Kinking leads can cause additional stress on the leads, possibly resulting in lead fracture.
- Do not suture directly over the lead body as this may cause structural damage. Use the lead anchoring sleeve to secure the lead lateral to the venous entry site.

- Lead or Active Can® electrodes in electrical contact during a high voltage therapy could cause current to bypass the heart, possibly damaging the ICD and leads. While the ICD is connected to the leads, make sure that no therapeutic electrodes, stylets, or guidewires are touching or connected by an accessory low impedance conductive pathway. Move objects made from conductive materials (e.g., an implanted guidewire) well away from all electrodes before a high voltage shock is delivered.
- If a pacing lead is abandoned rather than removed, it must be capped to ensure that it is not a pathway for currents to or from the heart.
- If a header port is unused on the ICD, the port must be plugged to protect the ICD.
- Refer to the lead technical manuals for specific instructions and precautions.

FOLLOW-UP TESTING

- Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant ICD testing should the patient require external rescue.
- Be aware that changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in nonconversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during testing is no assurance that conversion will occur post-operatively.

ICD EXPLANT AND DISPOSAL

- Interrogate the ICD, and program the ICD to OFF and disable ICD functions prior to explanting, cleaning, or shipping the ICD to prevent unwanted shocks.
- Return all explanted pulse generators and leads to Medtronic.
- Never incinerate the ICD due to the potential for explosion. The ICD must be explanted before cremation.

ENVIRONMENTAL AND MEDICAL THERAPY HAZARDS

Patients should be directed to avoid devices that generate strong electric or magnetic interference (EMI). EMI could cause malfunction or damage resulting in non-detection or delivery of unneeded therapy. Moving away from the interference source, or turning it off, usually allows the ICD to return to its normal mode of operation.

HOSPITAL AND MEDICAL ENVIRONMENTS

- **Electrosurgical cautery** could induce ventricular arrhythmias and/or fibrillation, or may cause device malfunction or damage. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the ICD and leads as possible (minimum of 15 cm [six inches]).
- **External defibrillation** may damage the ICD or may result in temporary and/or permanent myocardial damage at the electrode tissue interface as well as temporary or permanent elevated pacing thresholds. Minimize current flowing through the ICD and lead system by following these precautions when using external defibrillation on a patient with an ICD:

- Position defibrillation paddles as far from the ICD as possible (minimum of 13 cm [five inches]). Minimize current flowing through the ICD and lead system by positioning the defibrillation paddles perpendicular to the implanted ICD-lead system.
- Use the lowest clinically appropriate energy output (watt seconds).
- Confirm ICD function following any defibrillation.

- **High radiation sources** such as cobalt 60 or gamma radiation should not be directed at the ICD. If a patient requires radiation therapy in the vicinity of the ICD, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.
- **Lithotripsy** may permanently damage the ICD if it is at the focal point of the lithotripsy beam. If lithotripsy must be used, keep the ICD at least 2.5 to 5 cm [one to two inches] from the focal point of the lithotripsy beam.
- **Magnetic Resonance Imaging (MRI)** should not be used on patients who have an ICD because of the potential damage to the ICD.
- **Radio frequency ablation** procedure in a patient with an ICD could cause ICD malfunction or damage. RF ablation risks can be minimized by:
  - Programming the ICD to Off.
  - Avoiding direct contact between the ablation catheter and the implanted lead or ICD.
  - Positioning the ground plate so that the current pathway does not pass through or near the ICD system; i.e., place the ground plate under the patient's buttocks or legs.
  - Having defibrillation equipment available.

HOME AND OCCUPATIONAL ENVIRONMENTS

- **High voltage power transmission lines** could generate enough EMI to interfere with ICD operation if approached too closely.
- **Communication equipment** such as microwave transmitters, line power amplifiers, or high power amateur transmitters could generate enough EMI to interfere with ICD operation if approached too closely.
- **Commercial electrical equipment** such as arc welders, induction furnaces, or resistance welders could generate enough EMI to interfere with ICD operation if approached too closely.
- **Home appliances** which are in good working order and properly grounded do not usually produce enough EMI to interfere with ICD operation. There are reports of ICD disturbances caused by electrical hand tools or electric razors used directly over the ICD implant site.
- **Static magnetic fields.** Patients should avoid equipment or situations where they would be exposed to static magnetic fields (greater than 10 gauss or 1 millitesla magnetic fields) since it could suspend detection. Examples of magnetic sources that

could interfere with normal ICD operation include: stereo speakers, bingo wand, extractor wand, magnetic badges, or magnetic therapy products.

ELECTRONIC ARTICLE SURVEILLANCE (EAS)

- Electronic Article Surveillance (EAS) equipment such as retail theft prevention systems may interact with the ICD. Patients should be advised to walk directly through, and not to remain near an EAS system longer than is necessary.

CELLULAR PHONES

- The ICD has been tested to the frequency ranges used by the cellular phones included in Table 1. Based on this testing, the ICD should not be affected by the normal operation of such cellular phones.

- The ICD contains circuitry that allows usage without interaction (when programmed to nominal sensitivity) of all cellular phones having one of the transmission technologies listed in Table 1. These transmission technologies represent most of the cellular phones in use worldwide. Patients can contact their local cellular phone service provider to confirm that the provider uses one of these technologies.

Table 1. Cellular Phone Transmission Technologies

Transmission Technology	**Frequency Range**
Analog	
FM (Frequency Modulation)	824 - 849 MHz
Digital TDMA[a]	
North American Standards	
NADC[b] (TDMA - 50 Hz)	824 - 849 MHz
PCS[c] 1800	1850 - 1910 MHz
International Standards	
GSM[d]	880 - 915 MHz
DCS[e]	1710 - 1785 MHz
Digital CDMA	
CDMA - DS[f]	824 - 849 Mhz

[a]Time Division Multiple Access
[b]North American Digital Cellular
[c]Personal Communication System
[d]Global System for Mobile Communications
[e]Digital Cellular System
[f]Code Division Multiple Access - Direct Sequence

VI. Alternative Practices and Procedures

Alternative therapies for the indications described in Section II include the use of antiarrhythmic medication, electrical ablation and cardiac surgery, and other commercially available implantable cardioverter defibrillators, including in combination with pacemakers.

VII. Marketing History

The GEM™ DR system and the Model 6940 CapSureFix® lead are market released in those countries where regulatory approval has been obtained. The GEM™ DR system received the CE mark on March 23, 1998 and Canadian Notice of Compliance approval on June 8, 1998. The Model 6940 CapSureFix® lead received the CE mark on December 15, 1997 and Canadian Notice of Compliance approval on March 7, 1997. Over 800 GEM™ DR systems and Model 6940 CapSureFix® leads have been implanted worldwide. There were no reported instances where the device was withdrawn from the marketplace due to safety and effectiveness concerns.

VIII. Adverse Events

The clinical study of the GEM™ DR system included 300 GEM™ DR ICDs implanted in 300 patients worldwide, and 297 Model 6940 CapSureFix® leads implanted in 295 patients worldwide. Total GEM™ DR ICD exposure was 828 device months. Individual patient exposure averaged 2.8 months (ranging from 0 to 5.3 months).

Each adverse event was reviewed by an independent clinical events committee to determine whether it was related to the ICD system and/or the implantation procedure. There were a total of 15 deaths in the 300 patient clinical study; all were judged to be non-ICD related by the clinical events committee. The 15 deaths included: five non-sudden cardiac deaths attributed to congestive heart failure at 21, 50, 68, 77, and 89 days post-implant; five(4 non-sudden cardiac and one sudden cardiac) deaths due to cardiac and/or respiratory arrest or failure (at 1, 4, 20, 21, and 64 days post-implant); two non-sudden cardiac deaths due to cardiogenic shock (12 and 45 days post-implant); one sudden cardiac death due to electromechanical dissociation (118 days post-implant); one non-sudden cardiac death due to ischemic cardiomyopathy (28 days post-implant); and one non-sudden cardiac death due to pneumonia (64 days post-implant).

In the 300 patient clinical study one (1) device was explanted due to inappropriate VT detections.

The following adverse events were observed during the implant procedure (prior to skin closure): helix extension failure (4 patients); cut in ventricular lead (1 patient); ST elevation (1 patient); electromechanical dissociation (1 patient).

Tables 2 and 3 report the adverse events attributed to the ICD system and/ or implant procedure on a per patient and per patient-year basis in descending order of frequency. The tables list complications and observations that occurred more than once. Complications and observations that occurred only once are listed following Table 2 and Table 3.

Table 2. Complications Related to ICD System and/or Implant Procedure (All Patients, N=300): Multiple Complications

	# of Patients	% of Patients	# of Events	Events-per Patient Year
Complications[a] (total, including single complications)	24	8.0%	31	0.45
Atrial lead dislodgement	13	4.3%	13	0.19
Pneumothorax	5	1.7%	5	0.07
Ventricular lead dislodgement	3	1.0%	3	0.04
Hematoma	2	0.7%	2	0.03
Respiratory failure	2	0.7%	2	0.03

[a]Complications are adverse events that required invasive intervention. Complications that occurred in only one patient are listed following the table. Some patients had more than one type of adverse event.

Single Complications – Each of the following was observed once in one patient in the 300 patient clinical study: Atrial oversensing/undersensing; Failure to capture ventricle; Inappropriate ventricular detection; Increased pulse width threshold (atrium); Infection; and Protrusion under skin.

Table 3. Observations Related to ICD System and/or Implant Procedure (All Patients, N=300): Multiple Observations

	# of Patients	% of Patients	# of Events	Events-per Patient Year
Observations[a] (total, including single observations)	134	44.7%	189	2.74
Incisional pain	66	22.0%	67	0.97
Inappropriate ventricular detection	23	7.7%	29	0.42
Patient Alert™ tone triggered	11	3.7%	14	0.20
Atrial oversensing/ undersensing	10	3.3%	11	0.16
Hematoma	7	2.3%	7	0.10
Atrial fibrillation/flutter	6	2.0%	6	0.09
Incessant ventricular tachyarrhythmia	6	2.0%	6	0.09
Ecchymosis	4	1.3%	4	0.06
CHF/CHF exacerbation	3	1.0%	4	0.06
Increased DFT	3	1.0%	3	0.04
Ventricular oversensing	3	1.0%	3	0.04
Inadequate pace/ sense measurements (atrium)	2	0.7%	2	0.03
Increased pacing threshold	2	0.7%	4	0.06
Infection	2	0.7%	2	0.03
Pacemaker mediated tachycardia	2	0.7%	2	0.03
Palpitations	2	0.7%	2	0.03

[a]Observations are adverse events that did not require invasive intervention.
Observations that occurred in only one patient are listed following the table.
Some patients had more than one type of adverse event.

Single Observations – Each of the following was observed once in one patient in the 300 patient clinical study: Awareness of ventricular pacing; Bronchitis; Cardiogenic shock; Cellulitis; Cut in outer lead insulation of 6940 lead during repositioning; Delayed wound healing; Dizziness; Failure to defibrillate/cardiovert; Fatigue; Fever; Frequent spontaneous SVTs; Generator migration; Inadequate pace/sense measurements (ventricle); Insomnia; Lethargy; Multisystem failure; Near syncope; Pericardial effusion; Pneumothorax; Pulmonary edema; Respiratory failure; Subclavian vein thrombosis; and VF therapy delivered despite spontaneous episode termination.

IX. Potential Adverse Events

Adverse events including those reported in Tables 2 and 3 associated with ICD systems include: acceleration of arrhythmias (caused by ICD); air embolism; bleeding; chronic nerve damage; erosion; excessive fibrotic tissue growth; extrusion; fluid accumulation; formation of hematomas or cysts; inappropriate shocks; infection; keloid formation; lead abrasion and discontinuity; lead migration/dislodgement; myocardial damage; pneumothorax; potential mortality due to inability to defibrillate or pace; shunting current or insulating myocardium during defibrillation; thromboemboli, venous occlusion; and venous or cardiac perforation.

Patients susceptible to frequent shocks despite antiarrhythmic medical management could develop psychological intolerance to an ICD system that might include the following: dependency; depression; fear of premature battery depletion; fear of shocking while conscious; fear that shocking capability may be lost; and imagined shocking (phantom shock).

X. Summary of Studies

This section summarizes the studies performed to demonstrate that the GEM™ DR system and the Model 6940 CapSureFix® lead meet performance requirements and are safe and effective.

A. NONCLINICAL LABORATORY TESTING

1. GEM DR ICD Component and Subassembly Qualification Testing

All of the components and subassemblies of the GEM™ DR ICD were qualified for use in ICD applications. The qualification testing of the critical GEM™ DR ICD components and subassemblies qualification is summarized in Table 4. The qualification demonstrated that components and subassemblies performed according to specification and are of acceptable quality and reliability for use in the GEM™ DR ICD.

Table 4. GEM™ DR ICD Component/Subassembly Qualification Testing Summary

Component or Subassembly	# tested	Tests Performed and Acceptance Criteria	Results
Connector Module Subassembly	25	Meets all applicable requirements of the IS-1 (ISO 5841-3) and DF-1 (ISO 11318) international standards for connectors	Meets Acceptance Criteria
Low Power Hybrid Electronic Module Subassembly	130 76	Accelerated life (n=130) and high voltage pulsing (n=76) testing shall not cause hybrids to cease operation or exhibit parametric shifts that would prevent correct performance in end application.	Meets Acceptance Criteria
High Power Hybrid Electronic Module Subassembly	76	Accelerated life and charging life testing shall not cause hybrids to cease operation or exhibit parametric shifts that would prevent correct performance in end application.	Meets Acceptance Criteria
System Flex Assembly	29	No shorting of battery supply following fast recovery diode failure.	Meets Acceptance Criteria
Lithium-Silver Vanadium Battery (supplied by Medtronic's Promeon Division or Wilson Greatbatch, Ltd. (WGL)	16 Promeon 20 WGL	Accelerated discharge testing, environmental (shock, vibration, temperature extremes, constrained short-circuit at 35°C.) Batteries must conform to capacity, charge time, and dimensional requirements initially and following environmental exposures. Short-circuit samples must not lose hermeticity.	Meets Acceptance Criteria
High Voltage Output Capacitors	125 10 10 10	Qualified by similarity to the MicroJewel® Model 7221 HV cap, which is identical except for dimensions (2 mm shorter and 11 mm wider than 7271 HV cap), and meets the same specifications: Electrical Requirements: Capacitance 240μF ± 7.5%; DF 0.10 max; Leakage current: 200 μA max working; 300 μA max surge; unformed charge time 15 s max. Environmental: Must meet electrical requirements before and after environmental exposure (thermal shock, humidity, mechanical shock and vibration, solvents). Continuous Voltage Application Life Test: Must meet electrical requirements after 0, 168, 250, 500 and 1000 hours at 360V DC and 50°C. Charge/Discharge Application: Must meet electrical requirements after 0, 100, 500, 1000 and 2000 cycles of charging to 390V DC at 10 mA and 37°C.	Meets Acceptance Criteria
Activity Sensor	11	Qualified by similarity to identical component used in Thera-i® pacemakers. Temperature exposure and application life tests: Samples must meet capacitance (4.7 ± 0.7μF) and resistance (≤20 ohms) requirements after each 20°C increment from -18°C to 55°C and after 0, 168, 500 and 1000 hours temperature exposure.	Meets Acceptance Criteria

2. GEM™ DR ICD Device Qualification Testing

Device qualification testing was performed to ensure that the GEM™ DR ICD performs adequately in typical shipping, handling and operating environments. The device qualification testing is summarized in Table 5. The test results demonstrated that the GEM™ DR ICD will perform adequately in typical environments and is qualified for its intended use.

Table 5. GEM™ DR ICD Device Qualification Testing Summary

Test	# tested	Acceptance Criteria	Results
Environmental	22	Temperature Storage: Meets Section 26.2 of European Standard EN 45502-1	Meets Acceptance Criteria
	22	Mechanical Vibration: Meets Section 23.2 of European Standard prEN45502-2-2	
	22	Mechanical Shock: Meets Section 23.7 of European Standard prEN45502-2-2.	
Electromagnetic Compatibility	27	• Electromagnetic interference: Meets requirements of the 1975 AAMI Pacemaker Standard. Also meets performance standards at additional frequencies, including radiated continuous wave and pulsed electromagnetic fields and conducted continuous wave sinusoidal currents.	Meets Acceptance Criteria
	4	• Cellular Phone: Not susceptible to interference from analog or digital cellular telephones, including the following systems: AMPS, TDMA-50 (NADC), GSM, PCS, and CDMA.	
	22	• X-ray: Must withstand diagnostic levels (minimum 35 Rads).	
	22	• Electrosurgical Cautery: Must withstand spark cutting (150A/m2 rms); spark coagulating (400 A/m2 rms) and sine cutting (16 A/ms rms) modes and energies.	
	22	• Transthoracic Defibrillation: DC current leakage ≤10μA @1000V; ≤50μA @1500V.	
Post-shock Activity Sensor	3	The activity sensor/circuit must respond to a threshold of 55(+/-18) Pascals.	Meets Acceptance Criteria
Design Verification Testing	3	The electrical design, pacing and sensing, and delivered energy stability were evaluated by subjecting the ICD to various conditions (e.g. different loads, voltages, and temperatures) prior to testing. Device must perform appropriately over a broad range of conditions.	Meets Acceptance Criteria

3. Model 6940 CapSureFix® lead qualification testing

Qualification testing was performed on the Model 6940 CapSureFix® lead (full leads and lead subassemblies). The testing is summarized in Table 6 below. Each of the full leads and proximal subassemblies were exposed to thermal shock (-45°C to 70°C) and EtO sterilization as a preconditioning prior to qualification testing. The qualification testing demonstrated that the Model 6940 CapSureFix® lead met specifications and is qualified for its intended use.

Table 6. Model 6940 CapSureFix® Lead Qualification Testing Summary

Test	# Tested	Test and Acceptance Criteria	Results
Electrical: DC Resistance(58 cm)	31	Tip Conductor to Connector Pin: 27 ± 5 ohms Ring Conductor to Tip Conductor: 40 ± 6 ohms	Meets Acceptance Criteria
Lead Stiffness	33	≤ 3.6 psi max	Meets Acceptance Criteria
Leak Test	31	No visible leakage at 3x	Meets Acceptance Criteria
Insertion/Withdrawal	30	Meets IS-1 (ISO 5841-3)	Meets Acceptance Criteria
Composite Pull Strength	56 sub-assemblies	≥1.0 lbf	Meets Acceptance Criteria
Mechanical Flex Testing	22 sub-assemblies	Qualified by similarity to CapSureFix® Model 5068 lead, which has the identical subassembly. B50 ≥ 2 x 10^5 cycles. Meets CEN/CENELEC requirement.	Meets Acceptance Criteria
Mechanical Connections Strength		Qualified by similarity to CapSureFix® Model 5068 lead, which has the identical mechanical connections. The acceptance criteria are:	Meets Acceptance Criteria
	30	Electrode Ring to Outer Coil Weld: ≥ 2.5 lbs	
	30	Inner Coil/Connector Pin Weld: ≥ 1.0 lbs	
	59	Outer Coil/Connector Ring Weld: ≥ 2.5 lbs	
	30	Helix/Inner Coil Crimp: ≥ 3.0 lbs	
	33	Connector Pin Cap to Conductor Pin Crimp: ≥ 2.5 lbs	
Composite Torsional Strength	33	Must withstand min of 0.3in.-oz. of torque. (Composite torsional strength measures the twisting force the lead can withstand.)	Meets Acceptance Criteria
Anchoring Sleeve	31	Sliding Force 0.25 lb minimum Suture Force: no visual damaged	Meets Acceptance Criteria

4. Firmware, Software and System Testing

The GEM™ DR firmware, software, and system performance were evaluated under typical and unusual user scenarios, and stress and abuse testing, including feature interaction testing. Table 7 describes the GEM™ DR firmware verification testing, software verification testing, and system testing. All of the more than 400 GEM™ DR firmware requirements and more than 1000 GEM™ DR (Model 9960) software requirements were met.

System testing of the GEM™ DR system (GEM™ DR ICD, Model 9960 application software, Model 9790C programmer, Model 6940 CapSureFix® and other leads, Model 9466 magnet, accessories and support instruments) was performed to ensure that all system components work together appropriately under simulated clinical situations. System testing also included side-by-side strap-on testing comparing the programmability of GEM™ DR and Thera-i®activity responsiveness. The GEM™DR system performed appropriately during system testing.

The GEM™ DR system was analyzed to verify that hazard-mitigating actions were implemented for all components of the GEM™ DR system. The system hazard analysis verified that all mitigating actions were implemented.

Table 7. GEM™ DR Firmware, Software and System Testing

Test	# tested	Acceptance Criteria	Results
Firmware Verification Testing	n/a	Each firmware requirement must be met. The GEM DR has over 400 firmware requirements that specify the ICD functional performance.	Meets Acceptanc Criteria
Software Verification Testing	n/a	Each software requirement must be met. The Model 9960 (GEM DR) software has over 1,000 requirements that specify the software functional performance.	Meets Acceptanc Criteria
System Testing	n/a	GEM™ DR system (GEM™ DR ICD, Model 9960 application software, Model 9790C programmer, Model 6940 CapSureFix® and other leads, Model 9466 magnet, accessories and support instruments) must perform appropriately during simulated clinical situations, including typical and unusual user scenarios, stress and abuse testing, an feature interaction testing.	Meets Acceptanc Criteria
Side-by Side Strap-On Testing	3 GEM™ DR 1 Thera-i	The GEM™ DR activity response must be programmable to match the Thera-i® activity response.	Meets Acceptanc Criteria
System Hazard Analysis	n/a	Must verify that mitigating actions were implemented for all hazards identified during a system-level review of all components of the GEM DR system (including environmental or physiological factors, ICD, firmware, software, labeling, lead connector system and programmer system).	Meets Acceptanc Criteria

B. BIOCOMPATIBILITY

The biocompatibility of the tissue-contacting materials used in the GEM™ DR system and Model 6940 CapSureFix® lead has been established in previous PMA applications. These materials include platinum/iridium, polyurethane, silicone, silicone rubber, silicone rubber/titanium dioxide/barium sulfate, and titanium. These materials are all currently used in Medtronic's commercially available ICDs (including the Models 7219, 7220, 7221, 7223 Jewel® and MicroJewel® ICDs) and leads, and have a proven track record of biocompatibility. No new materials or processes were introduced with the GEM™ DR system or Model 6940 CapSureFix® lead that would introduce new issues of biocompatibility.

C. ANIMAL STUDIES

Animal studies were conducted to analyze the performance of the GEM™ DR system *in vivo* under conditions simulating human use. Acute and chronic (12 week) studies were performed in accordance with Good Laboratory Practice (GLP) regulations (21 CFR 58). The acute study was conducted in three (3) canines, and the chronic study in six (6) canines. The features evaluated in the animal studies included: dual chamber bradycardia pacing functions (including pacing modes, ventricular rate stabilization (VRS), ventricular safety pacing, and mode switch); dual chamber detection algorithm operation; dual tachyarrhythmia detection; shock avoidance during the atrial vulnerable period; patient alert sound level; subthreshold (painless) lead impedance measurement; DFTs; sensing; post-shock pacing thresholds; and external defibrillation. All evaluated features performed appropriately. Necropsy was performed on the six (6) canines following the chronic study. The gross pathology and histopathology showed no unusual results relating to the GEM™ DR Model 7271 ICD.

The Model 6940 CapSureFix® lead also was evaluated in a chronic (12 week) GLP study in 12 canines. The pacing thresholds, p-wave amplitudes, and pacing impedances were measured at implant and 1, 2, 3, 4, 8, and 12 weeks post-implant, and showed acceptable performance. Necropsy was performed on the 12 canines following the chronic study. The gross pathology and histopathology showed no unusual results relating to the Model 6940 CapSureFix® lead.

D. CLINICAL STUDIES

The ICD system clinical studies involved an acute study and an implant study.

Acute Study

The study was conducted in 62 patients undergoing ICD implantation or cardiac electrophysiology (EP) study using an external device that contained the GEM DR ICD dual and single chamber tachyarrhythmia detection algorithms.

Patients Studied – The patients (44 M / 18 F) had a mean age of 65.7 (range 33 - 87) years, and a mean left ventricular ejection fraction of 36.8% (range 10 - 70%) (n=37). Arrhythmia histories included non-sustained VT (24%), atrial fibrillation (19%), VT (18%) (non-exclusive).

Methods – The study evaluated the appropriateness of dual chamber sensing and tachyarrhythmia detection during induced and simulated cardiac arrhythmias. Arrhythmias (VT, VF, or SVT) were induced in 48 patients and the episode records evaluated for relative sensitivity and incremental specificity.

Results –The GEM™ DR dual chamber detection algorithm detected 67 out of 68 VT/VF episodes, for relative sensitivity of 98.5% *[89.9 - 99.8%]*, compared to the GEM™ DR single chamber detection algorithm. The GEM™ DR dual chamber detection algorithm discriminated 43 of 60 non-VT/VF episodes that had incorrectly been detected as VT/VF by the single chamber algorithm, for incremental specificity of 77.4% *[63.7 - 87.0%]*. No adverse interactions between sensing, pacing and detection were observed. No adverse events occurred during the study.

Table 8. Acute Study Results

Relative Detection Sensitivity, per VT/VF Episode: Dual Chamber Algorithm Relative to Single Chamber Algorithm		
	Relative Sensitivity[a] (%)	**Detections of VT/VF (#) by dual chamber algorithm[b]**
Acute Study, n=30[c] *[95% c.i.]*	98.5% *[89.9 - 99.8%]*	67 / 68[e] (98.5%)
Incremental Detection Specificity, per VT/VF Episode: Dual Chamber Algorithm Relative to Single Chamber Algorithm		
	Incremental Specificity[a](%))	**Discrimination of non-VT/VF by dual chamber algorithm[b]**
Acute Study, n=32[d] *[95% c.i.]*	77.4% *[63.7 - 87.0%]*	43 / 60[f] (71.7%)

[a]As adjusted for multiple episodes within a patient, based on the Generalized Estimating Equations Model with exchangeable correlation.
[b]Episode data recorded by the external device using the GEM™ DR dual and single chamber detection algorithms.
[c]30 patients with one or more induced VT/VF episodes.
[d]32 patients with one or more spontaneous SVT episodes.
[e]Detections of VT/VF episodes by the single chamber algorithm are stated as the denominator.
[f]Detections of non-VT/VF episodes by the single chamber algorithm are stated as the denominator.

Implant Study

This was a non-randomized, prospective study of 300 patients implanted with the GEM™ DR in the U.S., Europe, Canada and Australia. Most (295 patients) also received a Model 6940 CapSure Fix® lead. The mean implant duration was 2.8 months (range 0 to 5.3 months), with a cumulative implant duration of 828 device months.

Patients Studied – The patients (238 M / 62 F) had a mean age of 63.5 (range 13 to 90) years and a left heart ventricular ejection fraction of 37.5% (10% to 82%). The primary indications for implant included ventricular arrhythmias (141, 47%), ventricular arrhythmias and sudden cardiac death (101, 34%) and sudden cardiac death (52, 17%). Cardiovascular history included coronary artery disease and myocardial infarction (176, 59%), dilated cardiomyopathy (89, 30%), congestive heart failure (78, 26%) and hypertension (79, 26%) (non-exclusive).

Methods – The primary objective was to demonstrate unanticipated device related effect [1](UADRE) -free survival greater than 90% (lower confidence interval) at three months post-implant. Patients underwent standard ICD implantation and were evaluated at one month and three months post-implant. The implant criterion was DFT ≤ 22J by the binary search method or 2 out of 2 successful defibrillations at ≤ 24J. Spontaneous VT/VF episodes were evaluated for relative sensitivity, incremental specificity, and episode

termination effectiveness using the ICD's stored episode records. Pacing and sensing were evaluated via ambulatory monitoring of 51 patients. Activity sensor-driven pacing was evaluated in 20 patients who completed an exercise test. The heart rates at rest and during exercise were measured, and the physician reported whether or not the exertional rate[2] was acceptable for the patient's level of exercise. Patient Alert™ tone identifiability was evaluated via telephone monitoring at two months post-implant. Subthreshold (painless) lead impedance testing was performed at each visit (Figure 3). The Model 6940 CapSureFix® lead atrial pulse-width thresholds (Figure 2), pacing lead impedances (Figure 1), and p-wave amplitudes (Figure 4) were measured at implant and at 1 and 3 months post-implant.

Results – The implant study results are reported in Table 9 and Figures 1-7. The implant criterion was met with the initial lead system by 91.9% *[88.0 - 95.8%, 95% c.i.]* of patients using the binary search method and 88.0% *[81.8 - 94.1%, 95% c.i.]* of patients using the implant criterion of 2/2 defibrillations at ≤ 24J. The GEM™ DR dual chamber detection algorithm detected 795 out of 797 VT/VF episodes, for a relative sensitivity of 99.8% [*89.9 - 99.8%, 95% c.i.*], compared to the GEM™ DR single chamber detection algorithm. The GEM™ DR dual chamber detection algorithm discriminated 212 of 295 non-VT/VF episodes detected as VT/VF by the single chamber algorithm, for incremental specificity of 63.0% [*49.0 - 75.1 %, 95% c.i.*] compared to the GEM™ DR single chamber detection algorithm. The spontaneous episode termination effectiveness was 99.1% *[96.8 - 99.8%, 95% c.i.]*. All pacing and sensing functions evaluated via ambulatory monitoring performed as intended. All 20 patients evaluated were judged to have achieved an exertional heart rate that was acceptable for the patient's level of exercise. Patient Alert™ tones were correctly identified by the patient and clinician in 115 of the 119 patients tested (96.6% success *[91.6 - 99.2%, 95% c.i.]*). No unanticipated device-related effects (UADRE) were identified by the independent clinical events committee which determines whether events are related to the ICD system and/or the implantation procedure. Overall survival at 3 months was 94.7% *[89.5 - 97.3%. 95% c.i.]* (Figure 1). Complication-free survival at 3 months was 92.0% [*88.3 - 94.6%, 95% c.i.*] (Figure 2). The UADRE-free survival at 3 months was 100% *[95.5 - 100.0%, 95% c.i.]* (Figure 3). High voltage lead impedances measured by the subthreshold (painless) method are reported in Figure 4. The Model 6940 CapSureFix® lead atrial pulse width thresholds, pacing lead impedances and p-wave amplitudes are reported in Figures 5-7.

[1]Any "serious [incapacitating, life threatening, or fatal] unanticipated clinical event related to the ICD," excluding random component failure and device misuse.

[2]At the end of stage 3 of the CAEP treadmill exercise challenge

Gender Bias - The percentage of men (79.3 percent) and women (20.7 percent) enrolled in this study was comparable to that reported from the Medtronic ICD (all models) device registry (79.6 percent men and 20.4 percent women). The gender distribution was not statistically different between the 7271 study population and the population represented in the device registry (p=0.90)

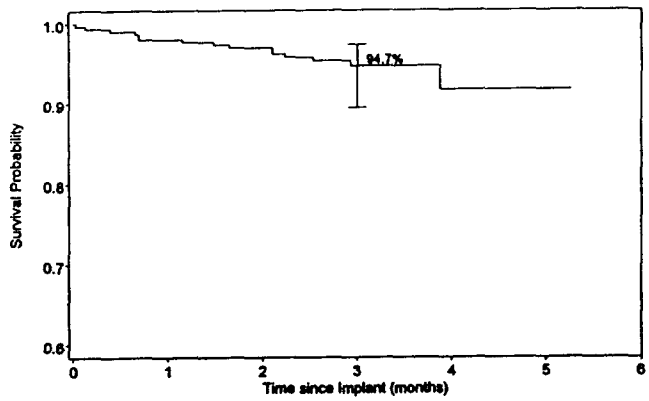
The device performance as measured by three safety and effectiveness parameters (implant criteria success, complication-free survival, and total survival) was assessed in both gender groups. There was no statistically significant difference between genders for any of these three parameters.

Table 9. Implant Study Results

Meeting Implant Criteria		
	Results	**# Successes /# Patients**
% of patients meeting implant criterion of DFT ≤ 22 J with initial lead system using binary search protocol [*95% c.i.*[a]]	91.9% *[88.0 - 95.8%]*	171 / 186
% of patients meeting implant criterion of 2/2 inductions at ≤ 24 J with initial lead system [*95% c.i.*[a]]	88.0% *[81.8 - 94.1%]*	95/108
Relative Sensitivity, per VT/VF Episode Dual Chamber Algorithm Relative to Single Chamber Algorithm		
	Relative Sensitivity[b] (%)	**Events of VT/VF (#) Detected by dual chamber algorithm[c]**
Implant Study, n=66[d] *[95% c.i.]*[b]	99.8% *[99.2 - 99.9%]*	795 / 797[e] (99.7%)
Incremental Detection Specificity, per VT/VF Episode Dual Chamber Algorithm Relative to Single Chamber Algorithm		
	Incremental Specificity[b](%)	**Discrimination of non-VT/VF by dual chamber algorithm[c]**
Implant Study, n=42[f] [*95% c.i.*][b]	63.0% *[49.0 - 75.1%]*	212 / 295[g] (71.9%)
Spontaneous Episode Effectiveness, per Episode		
	Effectiveness	**Successful terminations of VT/VF Episodes**
Spontaneous Episode Termination, n=64[h] [*95% c.i.*][b]	99.1% *[96.8 -99.8%]*	1147 / 1153 (99.5%)
Heart Rate During Activity Sensor-Driven Pacing		
	Rate at Rest	**Rate During Exercise**
Heart Rate (bpm) n=20[i] Mean ± s.d.	69.9 ± 14.2	104 ± 15.9

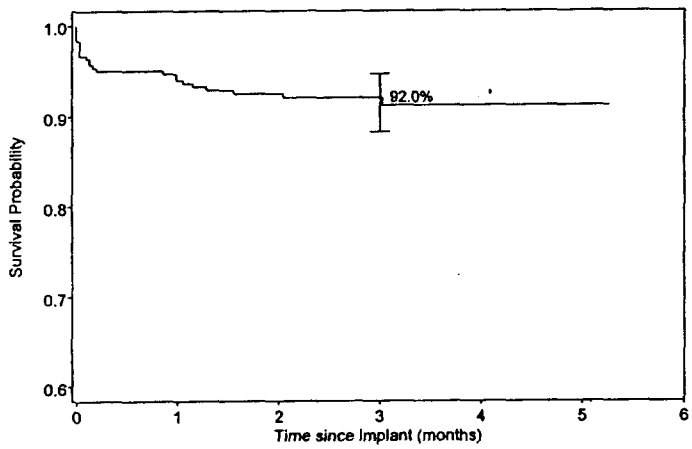
[a]Estimated by the exact binomial method.
[b]As adjusted for multiple episodes within a patient, based on the Generalized Estimating Equations Model with exchangeable correlation.
[c]Episode data recorded by the ICD memory using the GEM™ DR dual and single chamber detection algorithms.
[d]66 patients with one or more induced VT/VF episodes.
[e]Detections of VT/VF episodes by the single chamber algorithm are stated as the denominator
[f]42 patients with one or more spontaneous SVT episodes.
[g]Detections of non-VT/VF episodes by the single chamber algorithm are stated as the denominator.
[h]64 patients with one or more spontaneous VT/VF episodes.
[i]20 patients with activity sensor-driven pacing during an exercise test. All 20 were judged by the physician to have attained an adequate heart rate during exercise.

Figure 1. Overall Survival at 3 Months



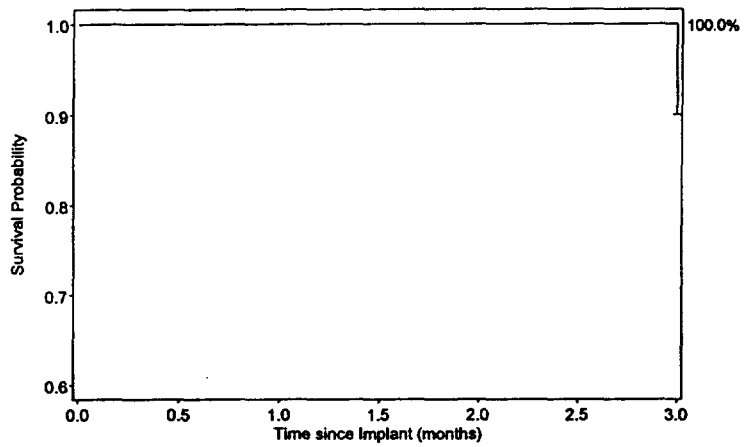
	Results	Successes (#)	Patients (#)
Overall survival at 3 months	94.7%	285	300
[95% c.i.]	*[89.5 - 97.3%]*		

Figure 2. Complication-Free Survival at 3 Months



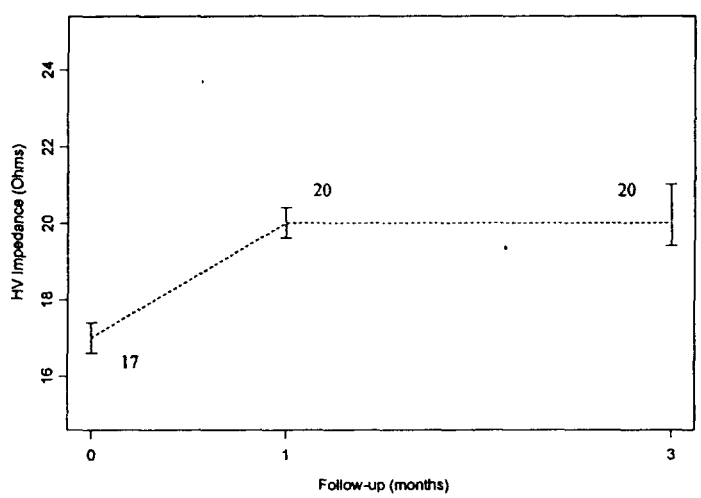
	Results	Successes (#)	Patients (#)
Complication-free survival at 3 months	92.0%	276	300
[95% c.i.]	*[88.3 - 94.6%]*		

Figure 3. UADRE-Free Survival at 3 Months



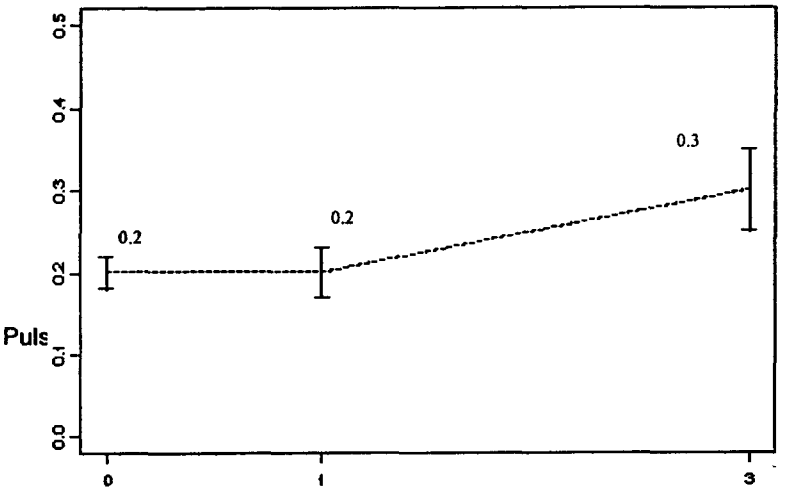
	Results	Successes (#)	Patients (#)
UADRE-free survival at 3 months	100.0%	117	117
[95% c.i.]	*[95.5 - 100.0%]*		

Figure 4. Median High Voltage (RV) Lead Impedance Measured by Subthreshold (Painless) Method at Implant, 1 Month, and 3 Months



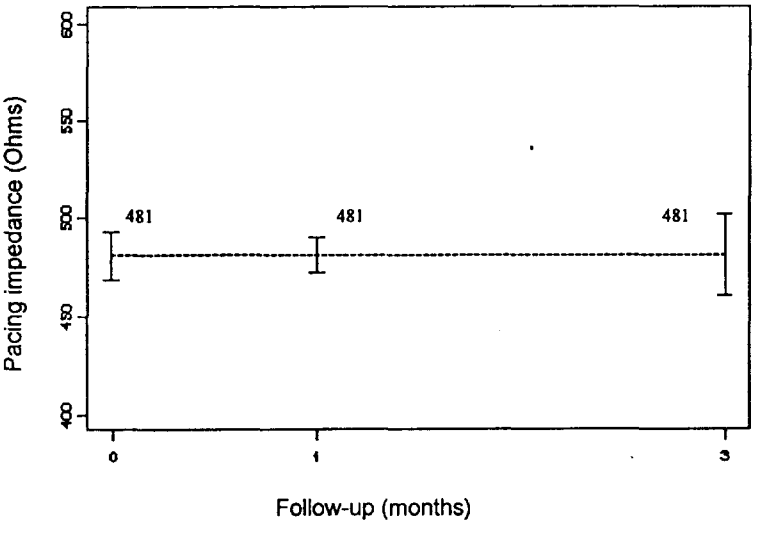
	Implant (N=294)	1 Month (N=277)	3 Months (N=80)
Mean (ohms)	17.2	20.3	19.8
Median (ohms)	17	20	20
95%c.i. (median)	16.6-17.4	19.6-20.4	19.4-21.0

Figure 5. Model 6940 CapSureFix® Lead Median
Atrial Pulse Width Thresholds at 1 Volt at Implant, 1 Month, and 3 Months



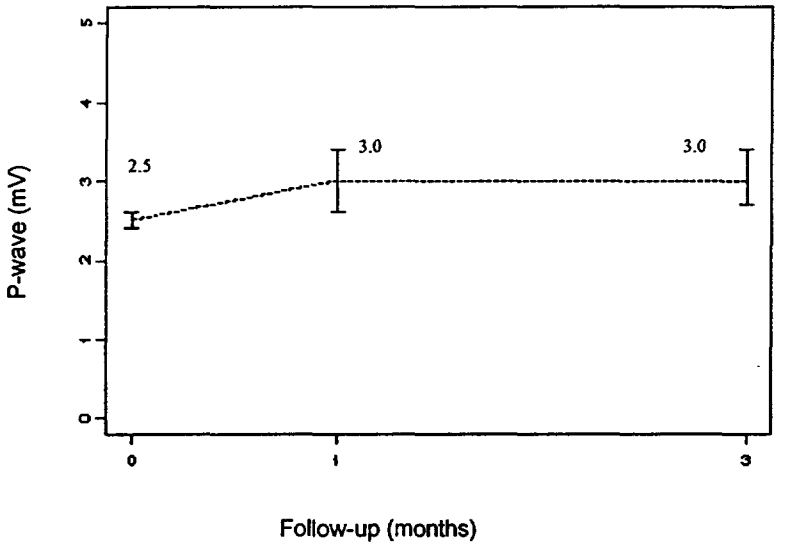
N	225	209	59
Mean (ms)	0.2	0.3	0.3
Median (ms)	0.2	0.2	0.3
95% c.i. (median)	0.18-0.22	0.17-0.23	0.25-0.35

Figure 6. Model 6940 CapSureFix® Lead Median
Atrial Pacing Impedances at Implant, 1 Month, and 3 Months



N	294	279	80
Mean (ohms)	493	478	492
Median (ohms)	481	481	481
95% c.i. (median)	469-493	472-490	461-502

Figure 7. Model 6940 CapSureFix® Lead Median
Atrial P-Wave Amplitudes at Implant, 1 Month, and 3 Months



N	288	261	77
Mean (mV)	2.7	2.8	2.6
Median (mV)	2.5	3.0	3.0
95% c.i. (median)	2.4-2.6	2.6-3.4	2.7-3.4

XI. Conclusions Drawn from Studies

The *in vitro* laboratory testing of the GEM™ DR system, its components and the Model 6940 CapSureFix® lead, demonstrate that the GEM™ DR system and Model 6940 CapSureFix® lead meet specifications and perform appropriately.

The *in vivo* animal studies of the GEM™ DR system and Model 6940 CapSureFix® lead demonstrate that the GEM™ DR system and Model 6940 CapSureFix® lead perform as expected.

An acute clinical study (n=62) and a 3 month implant clinical study (n=300) provide reasonable assurance that the GEM™ DR system and the Model 6940 CapSureFix® lead are safe and effective. The implant study primary objective of demonstrating unanticipated adverse device related effect (UADRE)-free survival greater than 90% (lower confidence interval) was met. No UADREs occurred during the study. UADRE-free survival, complication-free survival, and overall survival at three months were 100% *[90.0 - 100.0%, 95% c.i.]*, 92.0% *[88.3-94.6%, 95% c.i.]* and 94.7% *[89.5-97.3%, 95% c.i.]*, respectively. The spontaneous VT/VF episode termination effectiveness was 99.1% *[96.8-99.8, 95% c.i.]*. The adjusted relative sensitivity and incremental specificity of the dual chamber algorithm relative to the single chamber algorithm was 99.8% *[99.2 -*

99.9%, 95% c.i.] and 63.0% *[49.0 - 75.1%, 95% c.i.]* in the implant study, with similar results in the acute study.

The evidence summarized above represents valid scientific evidence that the GEM™ DR system and Model 6940 CapSureFix® lead provide reasonable assurance of safety and effectiveness when used as indicated in their labeling.

XII. Panel Recommendation

Pursuant to section 515(c) of the Food, Drug and Cosmetic Act (the Act) as amended by the Safe medical Devices Act of 1990, the PMA application was not referred to the Circulatory System Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA application substantially duplicates information previously reviewed by this panel.

XIII. FDA Decision

FDA found Medtronic, Inc.'s facilities in compliance with the Device Good Manufacturing Practices regulation (21 CFR part 820).

Based on the reviews of the PMA application for the Medtronic® Model 7271GEM™ DR Dual Chamber Implantable Cardioverter Defibrillator System with Model 9960(GEM™ DR) Software, Medtronic® Model 6940 CapSureFix® Lead and Model 9466 Patient Magnet, FDA determined that the device provides reasonable assurance of safety and effectiveness when used as indicated in the labeling, and approved the PMA application.

XIV.Approval Specifications

Directions for use: See labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.

Post-Approval Requirements and Restrictions: See approval order.

The Approval Order, Summary of Safety and Effectiveness Data, and labeling can be found on the Internet at http://www.fda.gov/cdrh/pmapage.html.

Medtronic

Medtronic® Model 7271 GEM™ DR Dual Chamber Implantable Cardioverter Defibrillator (ICD) System Prescriber's Package Insert

Caution: Federal Law (USA) limits this device to sale by or on the order of a physician.

Nominal Specifications

Maximum Shock Energy	Defibrillating Lead[a,b,c,d] Connection	Pacing Lead[b,d] Connection	Dimensions W x H x D	Volume	Mass
35 J	Two DF-1 (3.2 mm)	Two IS-1 bipolar (3.2 mm)	57 x 82 x 18 mm	62 cc	115 g

Case Material	Titanium
Header Materials	Polyurethane, silicone rubber
Power Supply	Lithium silver vanadium oxide (6.4 V nominal)

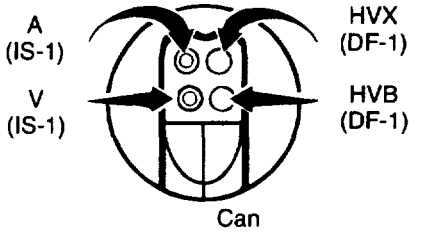
[a]The ICD case serves as a defibrillation electrode.

[b]For lead compatibility information, refer to the next page and the warning "Lead System:" on page 6.

[c]The DF-1 ports will not accept a 3.2 mm in-line bipolar lead.

[d]DF-1 refers to the international standard ISO 11318:1993.
IS-1 refers to ISO 5841-3:1992(E).

Lead Connections



Lead Compatibility

The ICD is designed to accept DF-1 and IS-1 bipolar lead connectors.[1] The Medtronic leads listed below are directly compatible with the GEM™ DR ICD.

Model	Placement	Fixation
Multipolar Pacing / Sensing / High Voltage Leads		
Sprint 6932	RV	Tines
Sprint 6942	RV and SVC coils	Tines
Sprint 6943	RV	Extendable Screw
Sprint 6945	RV and SVC coils	Extendable Screw
Transvene RV 6934S	RV	Tines
Transvene RV 6936	RV	Extendable Screw
IS-1 Bipolar Pacing / Sensing Leads		
SureFix 5072	Atrium	Fixed Screw
CapSure Fix 6940	Atrium	Extendable Screw
CapSure Fix 4568 / 5568	Atrium (J-curved)	Extendable Screw
CapSure Fix 4068 / 5068	Atrium or Ventricle	Extendable Screw
CapSure SP 5024M	Ventricle	Tines
DF-1 Unipolar Cardioversion / Defibrillation Leads		
Transvene 6933	SVC or CS	Passive
Transvene 6937	SVC	Passive
Transvene 6939	SQ patch	Suture
Model 6721	Epicardial Patch	Suture

[1] DF-1 refers to the international standard ISO 11318:1993.
IS-1 refers to ISO 5841-3:1992(E).

Created by Cardiovascular Technical Communications

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1 DEVICE DESCRIPTION

The Model 7271 GEM™ DR Dual Chamber Implantable Cardioverter Defibrillator (ICD) System (GEM™ DR system) is a multiprogrammable, implantable cardioverter defibrillator that monitors and regulates a patient's heart rate by providing ventricular arrhythmia therapy and single or dual chamber bradycardia pacing.

The Model 7271 GEM™ DR ICD, along with the Model 6940 CapSure Fix® or other compatible commercially available pace/sense leads and cardioversion/ defibrillation leads, constitutes the implantable portion of the ICD system. The lead systems for the GEM™ DR system are implanted using either transvenous or transthoracic techniques. The Model 9790C programmer, Model 9960E software, Model 9466 Patient Magnet, and a telemetry programming head constitute the external portion of the ICD system.

2 INDICATIONS AND USAGE

The GEM™ DR system is indicated for use in patients who are at risk of sudden death due to ventricular arrhythmias and have experienced one of the following situations:

- survival of at least one episode of cardiac arrest (manifested by loss of consciousness) due to a ventricular tachyarrhythmia
- recurrent, poorly tolerated, sustained ventricular tachycardia (VT)

Note: The clinical outcome for hemodynamically stable VT patients is not fully known. Safety and effectiveness studies have not been conducted.

3 CONTRAINDICATIONS

Do not use the GEM™ DR system in:

- Patients whose ventricular tachyarrhythmias may have transient or reversible causes, such as:
  - acute myocardial infarction,
  - digitalis intoxication,
  - drowning,
  - electrocution,
  - electrolyte imbalance,
  - hypoxia,
  - sepsis
- Patients with incessant VT or VF
- Patients who have a unipolar pacemaker
- Patients whose primary disorder is bradyarrhythmias or atrial arrhythmias.

4 WARNINGS AND PRECAUTIONS

- **Resuscitation availability.** Do not perform ICD testing unless an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are readily available.
- **Lead system.** Do not use another manufacturer's lead system without demonstrated compatibility as undersensing of cardiac activity and failure to deliver necessary therapy could result.
- **Electrical isolation.** Do not permit the patient to contact grounded equipment which could produce hazardous leakage current. Resulting arrhythmia induction could result in the patient's death.
- **Avoiding shock during handling.** Program the ICD to OFF during surgical implant and explant, or post-mortem procedures, because the ICD can deliver a serious shock if you touch the defibrillation terminals while the ICD is charged.

4.1 Sterilization, Storage, and Handling

- **Resterilization.** Do not resterilize and re-implant an explanted ICD.
- **"Use Before" Date.** Do not implant the ICD after the "Use Before" date, because the battery's longevity could be reduced.
- **If package is damaged.** Do not use the ICD or accessories if the packaging is wet, punctured, opened, or damaged, because the integrity of the sterile packaging might be compromised. Return the ICD to Medtronic.
- **ICD storage.** Store the ICD in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference to avoid ICD damage. Store and transport the ICD between -18 to 55 °C (0 to 131 °F), because temperatures outside this range could damage the ICD.

- **Equilibration.** Allow the ICD to reach room temperature before programming or implanting the ICD, because rapid temperature changes could affect initial ICD function.

4.2 Implantation and ICD Programming

- Infrequent charging of the high voltage capacitors could extend the ICD charge time. Program the ICD to condition the capacitors automatically, or perform a test charge to form the capacitors manually every six months (if the ICD has not charged to its maximum energy).
- Use only Medtronic programmers and application software to communicate with the ICD.
- Positioning a magnet or the programming head over the ICD suspends detection and treatment. The magnet does not alter bradycardia therapy.
- **End of Life (EOL).** Replace the ICD when the programmer displays an EOL message and a battery voltage of 4.57 volts or less. Immediate replacement is recommended if the programmer displays a Charge Circuit Timeout or Charge Circuit Inactive message.
- Program ICD parameters such as sensitivity thresholds and VT and VF detection intervals according to the recommendations in the technical manual.

4.3 Lead Evaluation and Lead Connection

- For lead resterilization, use ethylene oxide only. Do not resterilize more than one time.
- Do not tie a ligature directly to the lead body, tie it too tightly, or otherwise create excessive strain at the insertion site as this can damage the lead.

- Do not immerse leads in mineral oil, silicone oil, or any other liquid.
- Do not grip the lead with surgical instruments.
- Do not use excessive force or surgical instruments to insert a stylet into a lead.
- Use the same polarity evaluated during testing when connecting the leads to the ICD to ensure defibrillation effectiveness.
- If a thoracotomy is required to place epicardial patches, it should be done during a separate procedure to reduce the risk of morbidity and mortality.
- Do not place the patch lead over nerve tissue as this can cause nerve damage.
- Place the patch lead with the conducting coil side facing the heart to ensure delivery of energy to the heart.
- Place the sutures well outside the coil of the patch lead or in the area between the coils to avoid possible coil fracture.
- If countershock is unsuccessful using external paddles, adjust the external paddle position (e.g., anterior-lateral to anterior-posterior) and be sure that the external paddle is not positioned over the patch.
- Do not fold, alter, or remove any portion of the patch, because it could compromise electrode function or longevity.
- Do not use ventricular transvenous leads in patients with tricuspid valve disease or a mechanical prosthetic tricuspid valve. Use with caution in patients with a bioprosthetic valve.
- Use the correct suture sleeve (when needed) for each lead to immobilize the lead and protect it against damage from ligatures.
- Ensure that the defibrillation lead impedance is greater than 10 ohms. An impedance below 10 ohms could damage the ICD.

- Do not kink the leads. Kinking leads can cause additional stress on the leads, possibly resulting in lead fracture.
- Do not suture directly over the lead body as this may cause structural damage. Use the lead anchoring sleeve to secure the lead lateral to the venous entry site.
- Lead or Active Can® electrodes in electrical contact during a high voltage therapy could cause current to bypass the heart, possibly damaging the ICD and leads. While the ICD is connected to the leads, make sure that no therapeutic electrodes, stylets, or guidewires are touching or connected by an accessory low impedance conductive pathway. Move objects made from conductive materials (e.g., an implanted guidewire) well away from all electrodes before a high voltage shock is delivered.
- If a pacing lead is abandoned rather than removed, it must be capped to ensure that it is not a pathway for currents to or from the heart.
- If a header port is unused on the ICD, the port must be plugged to protect the ICD.
- Refer to the lead technical manuals for specific instructions and precautions.

4.4 Follow-up Testing

- Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant ICD testing should the patient require external rescue.
- Be aware that changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in nonconversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during testing is no assurance that conversion will occur post-operatively.

4.5 ICD Explant and Disposal

- Interrogate the ICD, and program the ICD to OFF and disable ICD functions prior to explanting, cleaning, or shipping the ICD to prevent unwanted shocks.
- Return all explanted pulse generators and leads to Medtronic.
- Never incinerate the ICD due to the potential for explosion. The ICD must be explanted before cremation.

4.6 Environmental and Medical Therapy Hazards

Patients should be directed to avoid devices that generate strong electric or magnetic interference (EMI). EMI could cause malfunction or damage resulting in non-detection or delivery of unneeded therapy. Moving away from the interference source, or turning it off, usually allows the ICD to return to its normal mode of operation.

4.6.1 Hospital and Medical Environments

- Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause device malfunction or damage. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the ICD and leads as possible (minimum of 15 cm [six inches]).
- **External defibrillation** may damage the ICD or may result in temporary and/or permanent myocardial damage at the electrode tissue interface as well as temporary or permanent elevated pacing thresholds. Minimize current flowing through the ICD and lead system by following these precautions when using external defibrillation on a patient with an ICD:
  - Position defibrillation paddles as far from the ICD as possible (minimum of 13 cm [five inches]). Minimize current flowing through the ICD and lead system by positioning the defibrillation paddles perpendicular to the implanted ICD-lead system.

- Use the lowest clinically appropriate energy output (watt seconds).
- Confirm ICD function following any defibrillation.

- **High radiation sources** such as cobalt 60 or gamma radiation should not be directed at the ICD. If a patient requires radiation therapy in the vicinity of the ICD, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.
- **Lithotripsy** may permanently damage the ICD if it is at the focal point of the lithotripsy beam. If lithotripsy must be used, keep the ICD at least 2.5 to 5 cm [one to two inches] from the focal point of the lithotripsy beam.
- **Magnetic Resonance Imaging (MRI)** should not be used on patients who have an ICD because of the potential damage to the ICD.
- **Radio frequency ablation** procedure in a patient with an ICD could cause ICD malfunction or damage. RF ablation risks can be minimized by:
  - Programming the ICD to **Off**.
  - Avoiding direct contact between the ablation catheter and the implanted lead or ICD.
  - Positioning the ground plate so that the current pathway does not pass through or near the ICD system; i.e., place the ground plate under the patient's buttocks or legs.
  - Having defibrillation equipment available.

4.7 Home and Occupational Environments

- **High voltage power transmission lines** could generate enough EMI to interfere with ICD operation if approached too closely.
- **Communication equipment** such as microwave transmitters, line power amplifiers, or high power amateur transmitters could

generate enough EMI to interfere with ICD operation if approached too closely.

- **Commercial electrical equipment** such as arc welders, induction furnaces, or resistance welders could generate enough EMI to interfere with ICD operation if approached too closely.
- **Home appliances** which are in good working order and properly grounded do not usually produce enough EMI to interfere with ICD operation. There are reports of ICD disturbances caused by electrical hand tools or electric razors used directly over the ICD implant site.
- **Static magnetic fields.** Patients should avoid equipment or situations where they would be exposed to static magnetic fields (greater than 10 gauss or 1 millitesla) magnetic fields since it could suspend detection. Examples of magnetic sources that could interfere with normal ICD operation include: stereo speakers, bingo wand, extractor wand, magnetic badges, or magnetic therapy products.

4.7.1 Electronic Article Surveillance (EAS)

- Electronic Article Surveillance (EAS) equipment such as retail theft prevention systems may interact with the ICD. Patients should be advised to walk directly through, and not to remain near an EAS system longer than is necessary.

4.7.2 Cellular Phones

- The ICD has been tested to the frequency ranges used by the cellular phones included in Table 1. Based on this testing, the ICD should not be affected by the normal operation of such cellular phones.
- The ICD contains circuitry that allows usage without interaction (when programmed to nominal sensitivity) of all cellular phones having one of the transmission technologies listed in Table 1. These transmission technologies represent most of the cellular phones in use worldwide. Patients can contact their local cellular

phone service provider to confirm that the provider uses one of these technologies.

Table 1. Cellular Phone Transmission Technologies

Transmission Technology	Frequency Range
Analog	
FM (Frequency Modulation)	824 - 849 MHz
Digital TDMA[a]	
North American Standards	
NADC[b] (TDMA - 50 Hz)	824 - 849 MHz
PCS[c] 1800	1850 - 1910 MHz
International Standards	
GSM[d]	880 - 915 MHz
DCS[e]	1710 - 1785 MHz
Digital CDMA	
CDMA - DS[f]	824 - 849 MHz

[a]Time Division Multiple Access
[b]North American Digital Cellular
[c]Personal Communication System
[d]Global System for Mobile Communications
[e]Digital Cellular System
[f]Code Division Multiple Access - Direct Sequence

5 ADVERSE EVENTS

5.1 Observed Adverse Events

Clinical study of the GEM™ DR system included 300 ICDs implanted in 300 patients worldwide, and 297 Model 6940 CapSure Fix® leads implanted in 295 patients worldwide. Total ICD exposure was 828 device months. Individual patient exposure averaged 2.8 months (ranging from 0 to 5.3 months).

Each adverse event was reviewed by an independent clinical events committee to determine whether it was related to the ICD system and/or the implantation procedure. There were a total of 15 deaths in the 300 patient clinical study; all were judged to be non-ICD related by the clinical events committee. Table 2 reports the causes of patient death during the clinical study in descending order of frequency. Except where noted, all deaths were non-sudden cardiac deaths.

Table 2. Patient Deaths During the Clinical Study (N=300)

Cause of Deaths (15 deaths total)	**# of Patients**	**When occurred (days after implant)**
Congestive heart failure	5	21, 50, 68, 77, 89
Cardiac and/or respiratory arrest or failure	5[a]	1, 4, 20, 21, 64
Cardiogenic shock	2	12, 45
Electromechanical dissociation	1[a]	118
Ischemic cardiomyopathy	1	28
Pneumonia	1	64

[a]One sudden cardiac death.

In the 300 patient clinical study one (1) device was explanted due to inappropriate VT detections.

The following adverse events were observed during the implant procedure (prior to skin closure): helix extension failure (4 patients); cut in ventricular lead (1 patient); ST elevation (1 patient); electromechanical dissociation (1 patient).

Tables 3 and 4 report the adverse events attributed to the ICD system and/or implant procedure, on a per patient and per patient-year basis in descending order of frequency. The tables list complications and observations that occurred more than once. Complications and observations that occurred only once are listed following Table 3 and following Table 4.

Table 3. Complications Related to ICD System and/or Implant Procedure (All Patients, N=300): Multiple Complications

	# of Patients	% of Patients	# of Events	Events per Patient-Year
Complications[a] (total, including single complications)	**24**	**8.0%**	**31**	**0.45**
Atrial lead dislodgement	13	4.3%	13	0.19
Pneumothorax	5	1.7%	5	0.07
Ventricular lead dislodgement	3	1.0%	3	0.04
Hematoma	2	0.7%	2	0.03
Respiratory failure	2	0.7%	2	0.03

[a]Complications are adverse events that required invasive intervention. Complications that occurred in only one patient are listed following the table (page 16). Some patients had more than one type of adverse event.

Single Complications – Each of the following was observed once in one patient in the 300 patient clinical study: Atrial oversensing/ undersensing; Failure to capture ventricle; Inappropriate ventricular detection; Increased pulse width threshold (atrium); Infection; and Protrusion under skin.

Table 4. Observations Related to ICD System and/or Implant Procedure (All Patients, N=300): Multiple Observations

	# of Patients	% of Patients	# of Events	Events per Patient-Year
Observations[a] (total, including single observations)	**134**	**44.7%**	**189**	**2.74**
Incisional pain	66	22.0%	67	0.97
Inappropriate ventricular detection	23	7.7%	29	0.42
Patient Alert™ tone triggered	11	3.7%	14	0.20
Atrial oversensing/ undersensing	10	3.3%	11	0.16
Hematoma	7	2.3%	7	0.10
Atrial fibrillation/flutter	6	2.0%	6	0.09
Incessant ventricular tachyarrhythmia	6	2.0%	6	0.09
Ecchymosis	4	1.3%	4	0.06
CHF/CHF exacerbation	3	1.0%	4	0.06
Increased DFT	3	1.0%	3	0.04

[a] Observations are adverse events that did not require invasive intervention. Observations that occurred in only one patient are listed following the table (page 17). Some patients had more than one type of adverse event.

Table 4. Observations Related to ICD System and/or Implant Procedure (All Patients, N=300): Multiple Observations

	# of Patients	% of Patients	# of Events	Events per Patient-Year
Ventricular oversensing	3	1.0%	3	0.04
Inadequate pace/ sense measurements (atrium)	2	0.7%	2	0.03
Increased pacing threshold	2	0.7%	4	0.06
Infection	2	0.7%	2	0.03
Pacemaker mediated tachycardia	2	0.7%	2	0.03
Palpitations	2	0.7%	2	0.03

Single Observations – Each of the following was observed once in one patient in the 300 patient clinical study: Awareness of ventricular pacing; Bronchitis; Cardiogenic shock; Cellulitis; Cut in outer lead insulation of 6940 lead during repositioning; Delayed wound healing; Dizziness; Failure to defibrillate/cardiovert; Fatigue; Fever; Frequent spontaneous SVTs; Generator migration; Inadequate pace/sense measurements (ventricle); Insomnia; Lethargy; Multisystem failure; Near syncope; Pericardial effusion; Pneumothorax; Pulmonary edema; Respiratory failure; Subclavian vein thrombosis; and VF therapy delivered despite spontaneous episode termination.

5.2 Potential Adverse Events

Adverse events in alphabetical order, including those reported in Tables 3 and 4, associated with ICD systems include: Acceleration of arrhythmias (caused by ICD); Air embolism; Bleeding; Chronic nerve

damage; Erosion; Excessive fibrotic tissue growth; Extrusion; Fluid accumulation; Formation of hematomas or cysts; Inappropriate shocks; Infection; Keloid formation; Lead abrasion and discontinuity; Lead migration/dislodgement; Myocardial damage; Pneumothorax; Potential mortality due to inability to defibrillate or pace; Shunting current or insulating myocardium during defibrillation; Thromboemboli; Venous occlusion; Venous or cardiac perforation.

Patients susceptible to frequent shocks despite antiarrhythmic medical management could develop psychological intolerance to an ICD system that might include the following: Dependency; Depression; Fear of premature battery depletion; Fear of shocking while conscious; Fear that shocking capability may be lost; Imagined shocking (phantom shock).

6 CLINICAL STUDIES

The ICD system clinical studies involved an acute study and an implant study.

6.1 Acute Study

The study was conducted in 62 patients undergoing ICD implantation or cardiac electrophysiology (EP) study using an external device that contained the GEM™ DR ICD dual and single chamber tachyarrhythmia detection algorithms.

Patients Studied – The patients (44 M / 18 F) had a mean age of 65.7 (range 33 - 87) years, and a mean left ventricular ejection fraction of 36.8% (range 10 - 70%) (n=37). Arrhythmia histories included non-sustained VT (24%), atrial fibrillation (19%), VT (18%) (non-exclusive).

Methods – The study evaluated the appropriateness of dual chamber sensing and tachyarrhythmia detection during induced and simulated cardiac arrhythmias. Arrhythmias (VT, VF, or SVT) were induced in 48 patients and the episode records evaluated for relative sensitivity and incremental specificity.

Results – In the acute study, the GEM™ DR dual chamber detection algorithm demonstrated relative sensitivity (Table 6) of 98.5% [95% confidence interval of 89.9 - 99.8%] and incremental specificity (Table 7) of 77.4% [63.7 - 87.0%], compared to the GEM™ DR single chamber detection algorithm. No adverse interactions between sensing, pacing and detection were observed. No adverse events occurred during the study.

6.2 Implant Study

This was a non-randomized, prospective study of 300 patients implanted with the GEM™ DR in the U.S., Europe, Canada and

Australia. Most (295 patients) also received a Model 6940 CapSure Fix® lead. The mean implant duration was 2.8 months (range 0 to 5.3 months), with a cumulative implant duration of 828 device months.

Patients Studied – The patients (238 M / 62 F) had a mean age of 63.5 (range 13 to 90) years and a left heart ventricular ejection fraction of 37.5% (10% to 82%). The primary indications for implant included ventricular arrhythmias (47%), ventricular arrhythmias and sudden cardiac death (34%) and sudden cardiac death (17%). Cardiovascular history included coronary artery disease and myocardial infarction (59%), dilated cardiomyopathy (30%), congestive heart failure (26%) and hypertension (26%) (non-exclusive).

Methods – The primary objective was to demonstrate unanticipated device related effect[1] (UADRE) -free survival greater than 90% (lower confidence interval) at three months post-implant. Patients underwent standard ICD implantation and were evaluated at one month and three months post-implant. The implant criterion was DFT ≤ 22J by the binary search method or 2 out of 2 successful defibrillations at ≤ 24J. Pacing and sensing were evaluated via ambulatory monitoring of 51 patients. Activity sensor-driven pacing was evaluated in 20 patients who completed an exercise test. The heart rates at rest and during exercise were measured, and the physician reported whether or not the exertional rate[2] was acceptable for the patient's level of exercise (Table 9). Spontaneous VT/VF episodes were evaluated for therapy effectiveness (Table 8), relative sensitivity (Table 6), and incremental specificity (Table 7), using the ICD's stored episode records. Patient Alert™ tone identifiability was evaluated via telephone monitoring at two months post-implant. Subthreshold (painless) lead impedance testing was performed at each visit.

1. Any "serious [incapacitating, life threatening, or fatal] unanticipated clinical event related to the ICD," excluding random component failure and device misuse.

2. At the end of stage 3 of the CAEP treadmill exercise challenge

Results – The implant study results are detailed in Tables 5 through 9. Patient Alert™ tones were correctly identified by the patient and clinician in 115 of the 119 patients tested (96.6% success [95% confidence interval of 91.6 - 99.2%]). No unanticipated device-related effects (UADRE) were identified by the clinical events committee. All pacing and sensing functions evaluated via ambulatory monitoring performed as intended.

Table 5. Implant Study Results

Measure	Results	Successes (#)	Patients (#)
Results at Implant			
% of patients meeting implant criterion of DFT ≤ 22 J with initial lead system using binary search protocol *[95% confidence interval[b]]*	91.9% *[88.0 - 95.8%]*	171	186
% of patients meeting implant criterion of 2/2 inductions at ≤ 24 J with initial lead system *[95% confidence interval[b]]*	88.0% *[81.8 - 94.1%]*	95	108
Chronic Results			
Overall survival at 3 months *[95% confidence interval[a]]*	94.7% [89.5 - 97.3%]	285	300
Complication-free survival at 3 months *[95% confidence interval[a]]*	92.0% *[88.3 - 94.6%]*	276	300
UADRE-free survival at 3 months *[95% confidence interval[b]]*	100.0% *[95.5-100.0%]*	117	117

[a]Estimated by the Kaplan-Meier method.

[b]Estimated by the exact binomial method.

Table 6. Relative Detection Sensitivity, per VT/VF Episode: Dual Chamber Algorithm Relative to Single Chamber Algorithm

	Relative Sensitivity[a] (%)	Detections of VT/VF (#) by dual chamber algorithm[b]
Acute Study, n = 30[c] *[95% c.i.]*	98.5% *[89.9 - 99.8%]*	67 / 68[e] (98.5%)
Implant Study, n = 66[d] *[95% c.i.]*	99.8% *[99.2 - 99.9%]*	795 / 797[e] (99.7%)

[a]As adjusted for multiple episodes within a patient, based on the Generalized Estimating Equations Model with exchangeable correlation.

[b]Episode data recorded by the external device (acute study) or ICD memory (implant study), using the GEM™ DR dual and single chamber detection algorithms.

[c]30 patients with one or more induced VT/VF episodes.

[d]66 patients with one or more spontaneous VT/VF episodes.

[e]Detections of VT/VF episodes by the single chamber algorithm are stated as the denominator.

Table 7. Incremental Detection Specificity, per VT/VF Episode: Dual Chamber Algorithm Relative to Single Chamber Algorithm

	Incremental Specificity[a] (%)	Discrimination of non-VT/VF (#) by dual chamber algorithm[b]
Acute Study, n = 32[c] *[95% c.i.]*	77.4% *[63.7 - 87.0%]*	43 / 60[e] (71.7%)
Implant Study, n = 42[d] *[95% c.i.]*	63.0% *[49.0 - 75.1%]*	212 / 295[e] (71.9%)

[a]As adjusted for multiple episodes within a patient, based on the Generalized Estimating Equations Model with exchangeable correlation.

[b]Episode data recorded by the external device (acute study) or ICD memory (implant study), using the GEM™ DR dual and single chamber detection algorithms.

[c]32 patients with one or more induced SVT episodes.

[d]42 patients with one or more spontaneous SVT episodes.

[e]Detections of non-VT/VF episodes by the single chamber algorithm are stated as the denominator.

Table 8. Spontaneous Episode Termination Effectiveness, per Episode

	Effectiveness[a] (%)	VT/VF Episodes (#)	Episodes Successfully Terminated (#)
Implant Study, n = 64[b] *[95% c.i.]*	99.1% *[96.8 - 99.8%]*	1153	1147

[a]As adjusted for multiple episodes within a patient, based on the Generalized Estimating Equations Model with exchangeable correlation. The unadjusted results are essentially the same.

[b]64 patients with one or more spontaneous VT/VF episodes.

Table 9. Heart Rate During Activity Sensor-Driven Pacing

	Rate at Rest n = 20[a]	Rate During Exercise n = 20[a]
Heart Rate (bpm) Mean ± s.d.	69.9 ± 14.2	104 ± 15.9

[a]20 patients with activity sensor-driven pacing during an exercise test. All 20 were judged by the physician to have attained an adequate heart rate during exercise.

7 PATIENT SELECTION AND TREATMENT

7.1 Individualization of Treatment

Pectoral or abdominal implant site – Evaluate the prospective patient's size and activity level to determine whether a pectoral or abdominal implant is suitable.

Exercise stress testing – If the patient's condition permits, use exercise stress testing to:

- Determine the maximum rate of the patient's normal rhythm
- Identify any supraventricular tachyarrhythmias
- Identify exercise induced tachyarrhythmias.

The maximum exercise rate or the presence of supraventricular tachyarrhythmias may influence selection of programmable parameters. Holter monitoring or other extended ECG monitoring also may be helpful.

Electrophysiologic (EP) testing – It is strongly recommended that candidates for ICD therapy have a complete cardiac evaluation including EP testing. EP testing should identify the classifications and rates of all the ventricular and atrial arrhythmias, whether spontaneous or induced during EP testing.

Drug resistant supraventricular tachyarrhythmias (SVTs) may initiate frequent unwanted device therapy. A careful choice of programming options is necessary for such patients.

Antiarrhythmic drug therapy – If the patient is being treated with antiarrhythmic or cardiac drugs, the patient should be on a maintenance drug dose rather than a loading dose at the time of ICD implantation. If changes to drug therapy are made, repeated arrhythmia inductions are recommended to verify ICD detection and conversion. The ICD also may need to be reprogrammed.

Changes in a patient's antiarrhythmic drug or any other medication that affects the patient's normal cardiac rate or conduciton can affect the rate of tachyarrhythmias and/or effectiveness of therapy.

Direct any questions regarding the individualization of patient therapy to Medtronic's representative at 1-800-PCD-INFO (1-800-723-4636).

7.2 Specific Patient Populations

Pregnancy - If there is a need to image the ICD, care should be taken to minimize radiation exposure to the fetus and the mother.

Nursing Mothers - Although appropriate biocompatibility testing has been conducted for this implant device, there has been no quantitative assessment of the presence of leachables in breast milk.

Pediatric Patients - This ICD has not been studied in patients younger than 13 years of age.

Geriatric Patients - Most (67%) of the patients receiving this ICD in clinical studies were over the age of 60 years see "Clinical Studies").

Handicapped and Disabled Patients - Special care is needed in using this ICD for patients using electrical wheelchairs or other electrical (external or implanted) devices.

8 PATIENT COUNSELING INFORMATION

Physicians should consider the following points in counseling the patient about this ICD:

- Persons administering CPR may experience the presence of voltage on the patient's body surface (tingling) when the patient's ICD system delivers a shock.
- Advise patients to contact their physician immediately if they hear tones coming from their ICD.
- Encourage patients to use identification cards (issued by Medtronic) and/or identification bracelets documenting their ICD system.

Discuss information in the Patient Manual (*Restoring the Rhythms of Life* and *Model 9466 Patient Magnet Instructions For Use*) with patients before and after ICD implantation so they are fully familiar with operation of the ICD. Advise patients how to obtain additional copies of the patient manuals.

9 CONFORMANCE TO STANDARDS

This ICD was developed in conformance with all or parts of the following standards:

- ISO 5841-3:1992(E), IS-1 IPG Connector Standard.
- ISO 11318:1993(E), DF-1 Defibrillator Connector Standard.
- EN45502 - Active Implantable Medical Devices, Part 1: General Requirements for Safety, Marking and Information to be provided by the Manufacturer, August 1997.
- prEN45502 - Active Implantable Medical Devices; Part 2-2: Particular Requirements for Active Implantable Medical Devices Intended to Treat Tachyarrhythmia (Includes Implantable Defibrillators), March 1998.
- IEC 601-1, Medical Electrical Equipment: General Requirements for Safety.

This information should not be used as a basis of comparisons among devices since different parts of the standards mentioned may have been used.

10 HOW SUPPLIED

The Model 7271 GEM™ DR is packaged one per package in a sterile package.

11 CLINICIAN USE INFORMATION

11.1 Physician Training

Physicians should be familiar with sterile ICD implant procedure and familiar with follow-up evaluation and management of patients with a defibrillator (or referral to such a physician).

11.2 Directions for Use

ICD operating characteristics should be verified at the time of implantation and recorded in the patient file. Complete the Device Registration Form and return it to Medtronic as it provides necessary information for warranty purposes and patient tracking.

The Model 7271 Product Information Manual (PIM) is a separate document supplied with each ICD. This manual includes product specifications, operating characteristics, and implant and follow-up recommendations. The GEM™ DR System Reference Guide (SRG), supplied with the 9960E software, provides complete programming instructions and recommendations. Copies can be obtained by contacting the Medtronic representative, or by calling 1-800-PCD-INFO (1-800-723-4636). The PIM and SRG were last updated in October 1998.

11.3 Maintaining Device Effectiveness

11.3.1 ICD Storage

FOR SINGLE USE ONLY. Do not resterilize and reimplant an explanted ICD. Medtronic has sterilized the ICD with ethylene oxide prior to shipment. Resterilizing the ICD is necessary if the seal on the sterile package is broken. Resterilization does not affect the "Use Before" date because this date is based on battery life and sterility.

Do not implant the ICD when:

- It has been dropped on a hard surface from a height of 45 cm (18 inches) or more because this could have damaged pulse generator components;
- Its storage package has been pierced or altered, because this could have rendered it non-sterile;
- It has been stored or transported outside the environmental temperature limits of -18 to 55 °C (0 to 131 °F), as the ICD circuitry may have been damaged; or
- Its "Use Before" date has expired, because this can adversely affect ICD longevity or sterility.

11.3.2 Sterilization Instructions

Do not resterilize the ICD or the torque wrench using an autoclave, gamma radiation, organic cleaning agents (e.g., alcohol, acetone, etc.), or ultrasonic cleaners.

Should sterilization be required:

- Repackage all items in a gas permeable container;
- Use a validated ethylene oxide gas process;
- Follow the manufacturer's operation instructions so long as the maximum temperature does not exceed 55 °C (131 °F);
- Store the resterilized components for an appropriate period to permit aeration of ethylene oxide gas.

12 PATIENT INFORMATION

Information for the patient is available in a separate booklet, *Restoring the Rhythms of Life*, from Medtronic. To obtain a copy, contact the Medtronic representative or call 1-800-PCD-INFO (1-800-723-4636). This information should be given to each patient with their ICD, and offered to the patient on each return visit or as deemed appropriate.

Restoring the Rhythms of Life was developed using patient and clinician input to ensure that it is understandable. *Restoring the Rhythms of Life* was last updated September 1998.

13 BIBLIOGRAPHY

Comprehensive reference material on all aspects of implantable cardioverter defibrillators:

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3. Estes M, Manolis AS, Wang P, Eds. *Implantable Cardioverter-Defibrillator.* New York, NY: Marcel Dekker, Inc. 1994.
4. Kroll MW, Lehmann MH, Eds. *Implantable Cardioverter-Defibrillator Therapy.* Norwell, MA: Kluwer Academic Publishers 1996.

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